

Appl. No.: 09/729578
Amdt Dated: December 9, 2003
Reply to office action of September 10, 2003

Amendments to the Specification:

Page 1, after the title, please replace paragraph [0001] (the first paragraph as amended in the preliminary amendment) with the following amended paragraph:

[0001] This patent document is a continuation claiming the benefit of the U.S. Patent Application, Serial Number 08/924,519; filed on September 5, 1997, now U.S. Patent 6,200,287.

Please replace paragraph [0046] (the second paragraph beginning on page 23) with the following amended paragraph:

[0046] A twentieth aspect of the present invention relates to an extracorporeal blood processing device that comprises a cassette member having a reservoir, at least first and second flexible tubing lines adjacently interconnected to the cassette member in predetermined spaced relation, a collection means interconnected to one of the flexible tubing lines, and an interfacing valve assembly having a moveable member selectively positionable to occlude one of the tubing lines, such that in a first mode of operation a separated blood component will be collected in the collection means, and in a second mode of operation the separated blood component will be diverted into the reservoir. In one embodiment, multiple sets of corresponding first and second tubing lines/collection means/valve assemblies are provided, with each of the sets providing for selective diversion of a blood component into a separate collection means or common reservoir. Utilization of this arrangement yields a compact disposable that can be readily mounted relative to the divert valve assemblies in a reliable manner.

Please replace paragraph [0048] (the second paragraph beginning on page 24) with the following amended paragraph:

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[0048] A twenty-second aspect of the present invention relates to the extracorporeal collection of both platelets and red blood cells utilizing the same blood processing vessel. More particularly, such method includes flowing blood from a donor/patient to a blood processing vessel and separating platelets from the blood within the blood processing vessel. At least a portion of the platelets is collected in a collection reservoir that is separate from the blood processing vessel. Further, the method includes separating red blood cells from the blood within the blood processing vessel and collecting at least a portion of the separated red blood cells within a red blood cell collection reservoir that is also separate from blood processing vessel. In one approach, the collection of platelets and red blood cells may be advantageously completed during separate time periods. For example, platelet collection may be completed prior to red blood cell collection. Alternatively, red blood cell collection may precede platelet collection. In another potential approach, red blood cells may be separated and collected concurrently with platelets and/or plasma.

Please replace paragraph [0098] (the second paragraph beginning on page 30) with the following amended paragraph:

[0098] Fig. 31 is an "AC interconnect screen" for the computer graphics interface of the apheresis system of Fig. 1;

Please replace paragraph [0190] (the first paragraph beginning on page 69) with the following amended paragraph:

[190] As noted above, the configuration of the channel 208 is desirable/important in a number of respects. As such, the dimensions of one embodiment of the channel 208 are provided herein and which may contribute to the functions of the channel 208 discussed below. The dimensions

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for one embodiment of the channel 208 are identified on Fig. 9B. All radii and thicknesses, etc., are expressed in inches.

Please replace paragraph [0207] (the second paragraph beginning on page 75) with the following amended paragraph:

[0207] $PF = \omega^2 \times R \times (v_{RBC}/W) \times V/Q_{IN}$, where:

Please replace paragraph [0209] (the fourth paragraph beginning on page 75) with the following amended paragraph:

[0209] ω = rotational velocity;

Please replace paragraph [0217] (the first paragraph beginning on page 77) with the following amended paragraph:

[0217] Increasing the packing factor beyond a certain point produces diminishing returns regarding the collection of blood component types. That is, further increases in packing factor may not produce correspondingly increased collection efficiencies and may in fact impede the collection of blood component types. It is believed that a packing factor ranging from about 4 to about 21, preferably from about 11 to 15, and more preferably about 13, is optimum for collection of most blood component types. It has been observed, however, that during red blood cell collection, an increased packing factor (i.e. > 13) may prove desirable to lower the level of white blood cells in the collected RBC product. The rotational velocity of the channel housing 204 may be adjusted based upon the inlet flows being provided to the blood processing vessel 352 to maintain the desired packing factor. For instance, the desired operating speed for the centrifuge housing 204 during the normal course of an apheresis procedure is about 3,000 RPM. However, this rotational speed may be reduced to "match" the inlet flow to the blood processing

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vessel 352 in order to retain the desired packing factor. Similarly, the rotational speed of the channel housing 204 may be increased to "match" an increased inlet flow to the blood processing vessel 352 in order to retain the desired packing factor.

Please replace paragraph [0220] (the first paragraph beginning on page 79) with the following amended paragraph:

[220] The blood processing vessel 352 is disposed within the channel 208 for directly interfacing with and receiving a flow of blood in an apheresis procedure. The use of the blood processing vessel 352 alleviates the need for sterilization of the channel housing 204 after each apheresis procedure and the vessel 352 may be discarded to provide a disposable system. There are initially two important characteristics regarding the overall structure of the blood processing vessel 352. The blood processing vessel 352 is constructed such that it is sufficiently rigid to be free standing in the channel 208. Moreover, the blood processing vessel 352 is also sufficiently rigid so as to load in the channel 208 having the above-identified configuration (i.e., such that the blood processing vessel 352 must be directed through the reduced width upper channel section 292 before passage into the larger width mid-channel section 300). However, the blood processing vessel 352 must also be sufficiently flexible so as to substantially conform to the shape of the channel 208 during an apheresis procedure.

Please replace paragraph [0258] (the third paragraph beginning on page 97) with the following amended paragraph:

[0258] The centrifuge rotor assembly 568 includes a number of additional features to facilitate the loading of the blood processing vessel 352 in the channel 208. Initially, the pinion 620 is radially offset in relation to the lower aperture 600 of the rotor body 592. In one embodiment, a

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reference axis laterally bisects the lower aperture 600 and may be referred to as the "zero axis". The axis about which the pinion 620 rotates is displaced from this "zero axis" by an angle of about 40 in the illustrated embodiment. An angle of -40 could also be used. Positioning the pinion 620 at an angle of "greater" than ± 40 will result in the pinion 620 beginning to interfere with the access to the loading aperture 597. Although the angle may be less than 40 and may even be 0, having the pinion 620 at 0 will result in the counterweights 608 potentially interfering with the access to the loading aperture 597. Based upon the foregoing, in Fig. 25 the pinion assembly 612 has therefore been rotated about the axis which the centrifuge rotor assembly 568 rotates for ease of illustration.

Please replace paragraph [0266] (the third paragraph beginning on page 101) with the following amended paragraph:

[0266] Once the flow of blood reaches the blood processing vessel 352, the rotational speed of the channel housing 204 is increased from about 1,500 RPM to about 2,500 RPM for a rotor diameter of about 10", preferably about 2000 RPM, such that blood being provided to the blood processing vessel 352 will be separated into the various blood component types even during the priming procedure. Once again, during this "second stage", the rotational velocity need not be fixed, but may vary. In order for a blood prime to be successful, a flow must be provided to the control port assembly 488 before any RBCs flows beyond the RBC dam 232 in a clockwise direction. This is again provided by the configuration of the channel 208.

Please replace paragraph [0270] (the second paragraph beginning on page 103) with the following amended paragraph:

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[0270] In the first stage 312, blood is separated into a plurality of layers of blood component types including, from the radially outermost layer to the radially innermost layer, RBCs, WBCs, platelets, and plasma. As such, the RBCs sediment against the outer channel wall 216 in the first cell separation stage 312. By configuring the RBC dam 232 such that it is a section of the channel 210 which extends further inwardly toward the rotational axis 324 of the channel housing 204, this allows the RBC dam 232 to retain separated red blood cells in the first stage 312.

Please replace paragraph [0280] (the first paragraph beginning on page 108) with the following amended paragraph:

[0280] In order to establish the desired packing factor, the operating speed of centrifuge rotor assembly 568 may be selectively established via control signals from blood component separation device 6, and the blood inlet flow rate to vessel 352 may be selectively controlled via control by blood component separation device 6 over pump assembly 1030. More particularly, increasing the rpm of centrifuge rotor assembly 568 and/or decreasing the inlet flow rate will tend to increase the packing factor, while decreasing the rpm and increasing the flow rate will tend to decrease the packing factor. As can be appreciated, the blood inlet flow rate to vessel 352 is effectively limited by the desired packing factor.

Please replace paragraph [0283] (the first paragraph beginning on page 109) with the following amended paragraph:

[0283] In one embodiment, where centrifuge rotor assembly 568 defines a rotor diameter of about 10 inches, and where a blood processing vessel 352 is utilized, as described hereinabove, it has been determined that channel housing 204 can be typically driven at a rotational velocity of about 3000 rpm to achieve the desired hematocrit during the setup and blood collection phases.

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Correspondingly, the blood inlet flow rate to vessel 352 should be established at below about 64.7 ml/min. The desired hematocrit can be reliably stabilized by passing about two whole blood volumes of reservoir 352 through reservoir 352 before the RBC collection phase is initiated.

Please replace paragraph [0290] (the first paragraph beginning on page 112) with the following amended paragraph:

[0290] After the storage solution has been added to the collected red blood cells in RBC reservoir 954, selective filtering may be desired to remove white blood cells. More particularly, for example, leukoreduction may be desired to establish a white blood cell count at $< 5 \times 10^8$ white blood cells/unit (e.g. about 250 ml.) to reduce any likelihood of febrile non-hemolytic transfusion reactions. Further, such filtering may be desirable to achieve a white blood cell count of $< 5 \times 10^6$ white blood cells/unit to reduce any risk of HLA (i.e. human leukocyte A) sensitization. If such leukoreduction is deemed appropriate, the red blood cell/ storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag 954 through a filter and into a new storage bag. Such commercially available red cell filter/bag kits include those available under the trade name "LEUKONET" from Hemosure located in Marlborough, Massachusetts and "RC 100", "RC50" and "BPF4" from Pall Corp. located in Glencone, New York.